

Healthcare Compliance



integrity
Ethics & Compliance Training

Topic 1 – Who Are Healthcare Providers?

1. **Video:** Define who healthcare providers are. Awareness of laws and pharmaceutical industry codes.
2. **Interactive Screen:** Advice on how to ensure you always treat healthcare providers fairly and respectfully.
3. **Scenario:** Pressure from supervisor to share negative information about a competitor's drug.
4. **Key Learning:** We treat healthcare providers with respect and that means telling the truth, and refusing to cut corners.
5. **Scenario:** Providing advice on selecting a drug to treat a medical condition.
6. **Key Learning:** If you are ever asked about differing opinions, you should be forthcoming that differing opinions do exist among researchers outside our company, although you should not comment beyond that.
7. **Assessment:** Five-question quiz on the content presented in this topic.

Topic 2 – Interacting with Healthcare Providers

1. **Interactive Screen:** Accurate and balanced information. Product promotion. Honesty, fairness, integrity. Compliance with Code of Conduct. Advance patient care. Never interfere or unduly influence a healthcare provider's decision.
2. **Interactive Screen:** Considerations when interacting with healthcare providers.
3. **Scenario:** Paying fair market value.
4. **Key Learning:** Paying fair market value is the ethical thing to do, and is also in line with our anti-bribery and corruption policy.
5. **Assessment:** Five-question quiz on the content presented in this topic.

Topic 3 – Marketing Best Practices

1. **Interactive Screen:** Vital we ensure our products are used properly and safely. Approved materials. Transparency. Marketing reviews. Authorizations vary by country.
2. **Scenario:** Marketing and off-label applications.
3. **Key Learning:** While it's beneficial to know the off-label benefits of a product, those benefits cannot be used to promote a product.
4. **Assessment:** Five-question quiz on the content presented in this topic.

Topic 4 – Interacting with Patients & Patient Advocacy Groups

1. **Video:** Treat patients with respect. Tell the truth. Keep our promises. Understand the communities we serve.
2. **Interactive Screen:** Guidelines for interacting with patients and patient advocacy groups.
3. **Scenario:** Finding patients for a clinical trial.
4. **Key Learning:** It's vital that we always interact with healthcare professionals honestly, fairly, and with integrity.
5. **Scenario:** Interacting with a patient who is taking part in a clinical trial.
6. **Key Learning:** We always tell patients the truth, even if it may not be what they want to hear.
7. **Scenario:** Request to fund a patient advocacy group.
8. **Key Learning:** Ensuring independence of the patient voice, being transparent in our interactions, and working cooperatively for the benefit of patients, are at the core of our standards.
9. **Assessment:** Five-question quiz on the content presented in this topic.

Topic 5 – Adverse Events

1. **Interactive Screen:** Define an adverse event. Reporting AEs. AEs that must be reported. Vendor responsibilities.
2. **Interactive Screen:** Individual's responsibility to report AEs. How AEs come to light. Examples of AEs. Reportable events. Collecting data on an AE.
3. **Scenario:** Blog that states one of our products made a poster nauseous.
4. **Key Learning:** Don't respond to posts that indicate AEs. When reporting an AE, you should include as much information as possible.
5. **Scenario:** Considerations when adding AE language to a vendor contract.
6. **Key Learning:** Vendors contracted by our company may be required to collect and report adverse events. We, and not the vendors, are responsible for ensuring appropriate AE reporting language is included in vendor contracts if needed.
7. **Assessment:** Five-question quiz on the content presented in this topic.

Topic 6 – Clinical Trial Transparency

1. **Interactive Screen:** Our standards. Responsibility to our patients. Patient consent. Public disclosure. Keeping pace with regulations.
2. **Scenario:** Assessing a clinical trial to identify areas of concern.
3. **Key Learning:** We MUST always act ethically when conducting research. If faced with compliance risk, contact your manager. If we fail to act ethically, we could negatively impact our relationships with patients and healthcare providers.
4. **Assessment:** Five-question quiz on the content presented in this topic.

Topic 7 – The False Claims Act

1. **Interactive Screen:** What are false claims? Penalties. Whistleblowers.
2. **Scenario:** Submitting a claim without the appropriate supporting documentation.

3. **Key Learning:** It is illegal to knowingly submit a false claim to the healthcare system. Doing so can open your practice to serious financial sanctions and damage your reputation.
4. **Scenario:** Office staff amending notes of a provider and releasing claims at a higher level or care provided.
5. **Key Learning:** It is your responsibility to consistently submit accurate claims that reflect the nature of services provided to the patient. Having good internal policies and procedures in place, such as a robust audit system, ensures effective care is provided by the physician and paid for by the patient's medical program.
6. **Assessment:** Five-question quiz on the content presented in this topic.

Topic 8 – The Anti-Kickback Statute

1. **Interactive Screen:** What is the Anti-Kickback Statute? Kickbacks. Penalties. Safe harbors. The Stark Law.
2. **Scenario:** Offer to cover travel and accommodation expenses, along with any other “speaking fees,” during the conference.
3. **Key Learning:** If you give or receive anything of value in return for patient referrals or are seen to arrange or recommend items that are paid for by a federal healthcare program, then you risk criminal prosecution under the Anti-Kickback Statute.
4. **Scenario:** Offer of a consultancy role by a medical device company to provide thought leadership and peer-to-peer assistance in research and development to help bring new devices to the market.
5. **Key Learning:** Any activity that increases the cost to a federally supported medical program is seen as a “red flag” to the government that may indicate a violation to the Anti-Kickback Statute or Stark Law.
6. **Assessment:** Five-question quiz on the content presented in this topic.

Topic 9 – Speaking Up

1. Summary screen that wraps up the module and provides details of where to go to speak up.
2. Attestation screen where learners attest that they will always help us remain compliant.